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EXAMINER
NOGUEROLA, ALEXANDER STEPHAN

ART UNIT	PAPER NUMBER
1753	

DATE MAILED: 09/09/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/844,929	KHAN, TAHIR S.	
	Examiner	Art Unit	
	ALEX NOGUEROLA	1753	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 June 2003* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-6 and 8-27* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4,8-15 and 17-27* is/are rejected.

7)☒ Claim(s) *5,6 and 16* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

Response to Amendment

1. Applicant's amendment of June 18, 2003 does not render the application allowable. New prior art has been found that reads, in whole or in part, on some of the newly amended claims.

Status of the Rejections Pending since the Office action of March 13, 2003

2. All previous rejections are withdrawn.

Claim Rejections - 35 USC § 112

3. Claims 8-10 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention:

a) Claim 8 recites the limitation "said redox reagent system" in lines 1-2. There is insufficient antecedent basis for this limitation in the claim.

4. Note that dependent claims will have the deficiencies of base and intervening claims.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

6. Claims 1-4, 8-12, 15, 17-20, 24, and 27 are rejected under 35 U.S.C. 102(e) as being anticipated by Maxwell et al. (US 6,325,917 B1).

Addressing claim 1, the Maxwell et al. reference teaches an electrochemical test strip (abstract) comprising

(a) a plurality of reaction zones defined by opposite working (2) and reference (12) electrodes separated by a spacer layer (7), wherein each of the reaction zones is defined by a bore through the spacer layer (8); and

(b) a reagent composition (5) present in each of the reaction zones.

See Figures 1 and 3 and column 5, lines 39-67.

Addressing claim 2, at least two reaction zones are shown in Figure 3.

Addressing claims 3 and 4, having the reagent compositions in the reaction zones the same or different is disclosed in col. 5, ll. 35-38.

Addressing claims 8-10, 18, 19, and 27, several enzyme and mediator combinations for the redox reagent system, including glucose oxidizing enzymes, are taught in *Table 1*, which spans columns 7 and 8 of the Maxwell et al. reference.

Addressing claims 11, 12, and 15, a palladium electrode is taught in col. 3, ll. 51-55.

Addressing claim 17, the Maxwell et al. reference teaches a method of determining the concentration of an analyte in a physiological sample, the method comprising

(a) applying the physiological sample (5) to an electrochemical test strip comprising a plurality of reaction zones defined by opposing working (2) and reference (12) electrodes separated by a spacer layer (8) and a reagent composition (5) present in each of the reaction zones, wherein each of the reaction zones are provided by a bore through the spacer layer. See Figures 1 and 3 and column 5, lines 39-67;

(b) detecting an electrical signal in the reaction zone using the opposing electrodes (col. 8, ll. 15-18); and

(c) relating the detected electrical signal to the amount of analyte in the sample (col. 8, ll. 15-18).

Addressing claim 20, employing a meter is implied by col. 8, ll. 15-18, which teaches measuring current.

Addressing claim 24, the Maxwell et al. reference teaches a system for use in determining The concentration of an analyte in a physiological sample, the system comprising

(a) an electrochemical test strip (abstract) comprising a plurality of reaction zones defined by opposing working (2) and reference (12) electrodes separated by a spacer layer (7) and a reagent composition (5) present in each of the reaction zones, wherein each of the reaction zones is defined by a bore through the spacer layer (8) (See Figures 1 and 3 and column 5, lines 39-67); and

(b) a meter (employing a meter is implied by col. 8, ll. 15-18, which teaches measuring current).

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

8. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

9. Claim 13 is rejected under 35 U.S.C. 103(a) as being unpatentable over Maxwell et al. (US 6,325,917 B1).

Addressing claim 1, the Maxwell et al. reference teaches an electrochemical test strip (abstract) comprising

(a) a plurality of reaction zones defined by opposite working (2) and reference (12) electrodes separated by a spacer layer (7), wherein each of the reaction zones is defined by a bore through the spacer layer (8); and

(b) a reagent composition (5) present in each of the reaction zones.

See Figures 1 and 3 and column 5, lines 39-67.

The Maxwell et al. reference does not mention the volume of the reaction zones; in particular, the reference does not mention reaction zones having a volume between 0.1 to 10 μl. However, the electrochemical test strip is clearly intended for use with small sample volumes suitable for reaction zones within a range close to that claimed by Applicant, because the electrodes are spaced apart about 0.5 mm or less (col. 4, ll. 21-25), the sample is applied to the reaction zone as a precise droplet (col. 3, ln. 64 – col. 4, ln. 1 and col. 7, ll. 12-16), and the rate of electro-oxidation of the anaylte is diffusion controlled (col. 4, ll. 17-21). Thus, barring evidence to the contrary, such as unexpected events, arranging the reaction zones to have a volume between 0.1 to 10 μl is just a matter of scaling the reaction zones of Maxwell et al. to the expected typical sample volume.

10. Claim 14 is rejected under 35 U.S.C. 103(a) as being unpatentable over Maxwell et al. (US 6,325,917 B1) in view of Hodges et al. (WO 97/18464).

Addressing claim 1, the Maxwell et al. reference teaches an electrochemical test strip (abstract) comprising

(a) a plurality of reaction zones defined by opposite working (2) and reference (12) electrodes separated by a spacer layer (7), wherein each of the reaction zones is defined by a bore through the spacer layer (8); and

(b) a reagent composition (5) present in each of the reaction zones.

See Figures 1 and 3 and column 5, lines 39-67.

Although the Maxwell et al. reference only specifically mentions palladium electrodes the reference teaches, through the Hodges et al. reference, that other metals, such as gold, may used for the reference electrode (col. 8, ll. 1-6 and col. 4, ll. 17-21 in Maxwell et al. and page 10, lines 7-14 of Hodges et al.). It would have been obvious to one with ordinary skill in the art at the time the invention was made to use a gold reference electrode as taught by Hodges et al. in the invention of Maxwell et a. because gold is a very good electrical conductor and has good corrosion resistance.

11. Claims 21, 23, 25, and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Maxwell et al. (US 6,325,917 B1) in view of Leader et al. (US 5,421,981).

Addressing claim 21, the Maxwell et al. reference teaches a kit for use in determining the concentration of an analyte in a physiological sample, the kit comprising

an electrochemical test strip (abstract) comprising a plurality of reaction zones defined by opposing working (2) and reference (12) electrodes separated by a spacer layer (7) and

a reagent composition (5) present in each of the reaction zones, wherein each of the reaction zones is defined by a bore through the spacer layer (8). See Figures 1 and 3 and column 5, lines 39-67.

The Maxwell et al. reference does not mention providing a means for obtaining a physiological sample nor an analyte standard.

Leader et al. teach a kit for use in determining the concentration of an analyte in a physiological sample comprising a means for obtaining a physiological sample and an analyte standard. See the abstract; Figure 1; col. 14, ll. 1-4; and col. 14, ll. 34-41. It would have been obvious to one with ordinary skill in the art at the time the invention was made to provide a means for obtaining a physiological sample and an analyte standard as taught by Leader et al. in the invention of Maxwell et al. because then the operator will not have to look for or separately store the appropriate analyte standard and means for obtaining the physiological sample. Including these items together in a kit will be more convenient for whoever is going to use the electrochemical test strip.

Addressing claim 23, providing a meter is implied by col. 8, ll. 15-18 of Maxwell et al., which teaches measuring current.

Addressing claim 25, the Maxwell et al. reference teaches a system for use in determining the concentration of an analyte in a physiological sample, the system comprising

(a) an electrochemical test strip (abstract) comprising a plurality of reaction zones defined by opposing working (2) and reference (12) electrodes separated by a spacer layer (7) and a reagent composition (5) present in each of the reaction zones, wherein each of the reaction zones is defined by a bore through the spacer layer (8) (See Figures 1 and 3 and column 5, lines 39-67); and

(b) a meter (employing a meter is implied by col. 8, ll. 15-18, which teaches measuring current).

The Maxwell et al. reference does not mention providing a means for obtaining a physiological sample.

Leader et al. teach a system for use in determining the concentration of an analyte in a physiological sample comprising a means for obtaining a physiological sample. See the abstract; Figure 1; col. 14, ll. 1-4; and col. 14, ll. 34-41. It would have been obvious to one with ordinary skill in the art at the time the invention was made to provide a means for obtaining a physiological sample as taught by Leader et al. in the invention of Maxwell et al. because then the operator will not have to look for or separately store the means for obtaining the

physiological sample. Including the physiological sample obtaining means in the system will be more convenient for whoever is going to use the electrochemical test strip.

Addressing claim 26, the Maxwell et al. reference teaches a system for use in determining the concentration of an analyte in a physiological sample, the system comprising

(a) an electrochemical test strip (abstract) comprising a plurality of reaction zones defined by opposing working (2) and reference (12) electrodes separated by a spacer layer (7) and a reagent composition (5) present in each of the reaction zones, wherein each of the reaction zones is defined by a bore through the spacer layer (8) (See Figures 1 and 3 and column 5, lines 39-67); and

(b) a meter (employing a meter is implied by col. 8, ll. 15-18, which teaches measuring current).

The Maxwell et al. reference does not mention providing an analyte standard.

Leader et al. teach a system for use in determining the concentration of an analyte in a physiological sample comprising an analyte standard. See the abstract; Figure 1; col. 14, ll. 1-4; and col. 14, ll. 34-41. It would have been obvious to one with ordinary skill in the art at the time the invention was made to provide an analyte standard as taught by Leader et al. in the invention of Maxwell et al. because then the operator will not have to look for or separately store the appropriate analyte standard. Including the analyte standard in the system will be more convenient for whoever is going to use the electrochemical test strip.

12. Claim 22 is rejected under 35 U.S.C. 103(a) as being unpatentable over Maxwell et al. (US 6,325,917 B1) in view of Leader et al. (US 5,421,981) as applied to Claims 21 and 23 above, and further in view of Guruswamy et al. (5,004,583). The Maxwell et al. reference as modified by the Leader et al. reference does not disclose a lance, although the Leader et al. reference does disclose a syringe (col. 14, ll. 38-41).

The Guruswamy et al. reference discloses that lances were used at the time of the invention to obtain small samples for test strips. See col. 1, ln. 65 – col. 2, ln. 6. It would have been obvious to one with ordinary skill in the art at the time the invention was made to provide a lancet as taught by the Guruswamy et al. reference, instead of, or in addition to, a syringe in the invention of Maxwell et al. as modified by Leader et al. because then small samples, such as a drop of blood, can be easily obtained and applied to the test strip.

Allowable Subject Matter

13. Claims 5, 6, and 16 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

14. The following is a statement of reasons for the indication of allowable subject matter:

a) Claim 5 requires each reaction zone to have a fluid ingress channel to provide for fluid communication between the reaction zone and the external environment of the test strip. No such fluid ingress channel is disclosed by the Maxwell et al. reference. As may be inferred from Figures 1 and 3, the reaction zones are directly exposed at both ends to the external environment of the test strip;

b) Claim 6 requires at least two reaction zones to have fluid ingress channels that merge to produce a single ingress channel to provide for fluid communication between the reaction zones and the external environment of the test strip. No such fluid ingress channels are disclosed by the Maxwell et al. reference. As may be inferred from Figures 1 and 3, the reaction zones are directly exposed at both ends to the external environment of the test strip; and

c) Claim 16 requires that the electrochemical test strip be present in a meter. As seen from the figures and col. 6, ll. 42-64 and col. 8, ll. 1-24, the electrodes are not disclosed as being configured to be present in a meter. The electrodes are disclosed as being in the form of continuous tapes or rotating discs and electrical contact is made through a clamping arrangement or springloaded contacts and the like.

Final Rejection

15. Applicant's amendment necessitated the new grounds of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to ALEX NOGUEROLA whose telephone number is (703) 305-5686. The examiner can normally be reached on M-F 8:30 - 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, NAM NGUYEN can be reached on (703) 308-3322. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0661.

Alex Noguerola

Alex Noguerola

9/05/03